



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS-4185-RCN]

RIN 0938-AK02

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Extension of Timeline to Finalize a Rulemaking

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Extension of timeline.

SUMMARY: The Social Security Act (the Act) requires us to publish a Medicare final rule no later than 3 years after the publication date of the proposed rule. This document announces an extension of the timeline for publication of a Medicare final rule in accordance with the Act, which allows us to extend the timeline for publication of the “Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021” final rule under exceptional circumstances.

DATES: As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the timeline for publication of a rule to finalize the November 1, 2018 proposed rule (83 FR 54982) is extended until November 1, 2022.

FOR FURTHER INFORMATION CONTACT: Joseph Strazzire, (410) 786-2775.

SUPPLEMENTARY INFORMATION: On November 1, 2018 (83 FR 54982), we published a proposed rule, “Medicare and Medicaid Programs; Policy and Technical Changes to the

Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,” that would revise the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) regulations to improve program efficiency and payment accuracy. The proposed rule discussed the Secretary’s authority to: (1) extrapolate in the recovery of RADV overpayments, starting with payment year 2011 contract-level audits; and (2) not apply a fee-for-service (FFS) adjuster to the RADV overpayment determinations.

Section 1871(a)(3)(A) of the Act requires the Secretary to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation. In accordance with section 1871(a)(3)(B) of the Act, the timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but may not be longer than 3 years except under exceptional circumstances. In addition, in accordance with section 1871(a)(3)(B) of the Act, the Secretary may extend the initial targeted publication date of the final regulation if the Secretary, no later than the regulation's previously established proposed publication date, publishes a notice with the new target date for publication, and such notice includes a brief explanation of the justification for the variation.

The final rule for the November 1, 2018 proposed rule should be published by November 1, 2021. However, we are unable to meet the 3-year timeline for publication of the previously referenced RADV-audit related provisions because of exceptional circumstances. Specifically, on October 26, 2018, just prior to the publication of the proposed rule, we published the FFS Adjuster Study. On December 27, 2018, we announced an extension of the comment period for the proposed RADV provisions of the rule until April 30, 2019 and a plan to release data underlying the FFS Adjuster study. On March 6, 2019 we announced the release of data underlying the FFS Adjuster study. On April 30, 2019, we announced an additional extension of the comment period for the RADV provision until August 28, 2019. We also announced that we

would be releasing additional data underlying the FFS Adjuster Study, including additional data containing Protected Health Information, to all parties who entered an applicable data use agreement and paid the required fee. Finally, on June 28, 2019, we released additional material related to the FFS Adjuster Study, and made a further request for public comment. Based on extensive public comments received on the proposed rule and subsequent FFS Adjuster study and related data along with delays resulting from the agency's focus on the COVID-19 public health emergency, we determined that additional time is needed to address the complex policy and operational issues that were raised.

This document extends the timeline for publication of the final rule for 1 year, until November 1, 2022.

Karuna Seshasai,

Executive Secretary to the Department,

Department of Health and Human Services.

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